

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESAL PRICE LITIGATION)	MDL No.1456
)	
)	Master File No. 01-CV-12257-PBS
)	Subcategory Case No. 06-11337-PBS
THIS DOCUMENT RELATES TO: <i>United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Boehringer Ingelheim Corporation, et al., Civil Action No. 07-10248-PBS</i>)	Judge Patti B. Saris
)	
)	Magistrate Judge Marianne B. Bowler
)	

**DEFENDANTS BOEHRINGER INGELHEIM CORPORATION AND BOEHRINGER
INGELHEIM PHARMACEUTICALS, INC.’S REPLY MEMORANDUM IN SUPPORT
OF THEIR MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

The Government's response confirms that it lacks any evidence to establish the disfavored remedy of piercing BIC's and BIPI's corporate veils to recover from them on FCA claims relating solely to Roxane drugs, much less evidence to hold these separate companies directly liable for Roxane's purported conduct. As an initial matter, the Government attempts to rewrite bedrock First Circuit law by claiming there is no requirement to show fraudulent intent as a predicate to piercing the corporate veil. The Government mischaracterizes the law to avoid its obligation to come forward with evidence. Instead, the Government spins a wholly unsupported story that, to avoid paying damages in this case, Roxane paid an inappropriate dividend to BIC more than two years after receiving a government subpoena. This far-fetched theory (inapplicable in any case to defendant BIPI) is contradicted by the factual record and creates no genuine issue of fact. Nor does the Government fare better in attempting to establish that Roxane did not operate independently from its parent or sister in light of the undisputed record.

Having no cognizable basis on which to pierce the corporate veil, the Government instead asserts an eleventh-hour direct liability theory that falls woefully short of meeting the stringent requirements under the FCA. As a punitive statute with treble damages, the FCA imposes specific causation and scienter requirements, which must be met for each defendant on a drug-by-drug basis. Specifically, the Government must show that BIC and BIPI not only had direct involvement in the setting and alleged marketing of AWP spreads for Roxane's drugs at issue, but did so either knowing Roxane's AWP's were false, or in reckless disregard of their falsity. There is no evidence of any of these elements. Nearly the entire universe of "facts" that the Government marshals are *immaterial* – and thus a nullity with respect to defeating summary judgment. Indeed, what is noticeably missing in the Government's response is evidence that BIC or BIPI had actual involvement in setting virtually any of the AWP's the Government claims are

false or in marketing any spreads. The Government repeatedly relies only upon a few isolated facts related to a few AWP decisions for a few of the drugs at issue that are insufficient to establish liability even for those drugs. The Government cannot maintain direct liability claims against BIC and BIPI for nine drugs over a ten year period on such threadbare evidence.

I. BIC AND BIPI ARE ENTITLED TO SUMMARY JUDGMENT ON THE GOVERNMENT'S VEIL-PIERCING CLAIM.

A. The Government Has No Evidence That BIC or BIPI Acted With Fraudulent Intent Or An Improper Purpose.

It is the Government, not BIC and BIPI, that is mistaken about the elements it must prove to pierce the corporate veil in this case. As the Government notes, under federal common law the overarching principle governing when the corporate form should be disregarded is whether it is warranted “in the interests of public convenience, fairness and equity” and the purpose of the federal statute at issue should be considered. (US Opp. to BIC/BIPI Mot. for SJ at 16-17) It is precisely from this standard that the three part test developed in *United Elec. Radio, and Mach. Workers of Am. v. 163 Pleasant St. Corp.* was derived. *163 Pleasant St.*, 960 F. 2d 1080, 1091-93 (1st Cir. 1992). Other courts have also been mindful of these principles when applying the *Pleasant St.* factors in other contexts, including in FCA cases. See *InterGen N.V. v. Grina*, 344 F.3d 134, 147-148 (1st Cir. 2003); *U.S. v. Mountzoures*, 376 F. Supp. 2d 13, 18 (D. Mass. 2005); *U.S. ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 39-40 (D. Mass. 2000) (FCA case). Thus, the three-part test outlined in *Pleasant St.* and relied upon by BIC and BIPI is premised on and consistent with the legal principles the Government references.

The Government's contention that there is no fraudulent intent requirement for piercing the corporate veil in the First Circuit misapplies the *Mass. Carpenters* decision. (US Opp. to BIC/BIPI Mot. for SJ at 19-20) The *Mass. Carpenters* case involved both ERISA and collective bargaining issues, and the Court determined that the unique “alter ego jurisprudence developed

in the labor law context” under which “there is no rule that wrongful motive is an essential element” was the “better and more apt model” for that particular situation. *Mass. Carpenters Central Collection Agency v. Belmont Concrete Corp.*, 139 F.3d 304, 308 (1st Cir. 1998).¹ The Court thus distinguished its decision in *Pleasant St.*, which was also an ERISA case but where it applied a fraudulent intent requirement, on the basis that it addressed the question of personal jurisdiction in an ERISA case, rather than substantive liability. (*Id.*) The *Mass. Carpenters* decision cannot be read to eliminate the fraudulent intent requirement when other statutes are at issue.

Indeed, outside the labor law and ERISA contexts, courts in the First Circuit have continued to require a finding of fraudulent intent in order to hold one corporation liable for the acts of another in federal statute cases, including the FCA. *See InterGen N.V.*, 344 F.3d at 147-148; *U.S. ex rel. Kneepkins*, 115 F. Supp. 2d at 39-40. Thus, while the Government spends several pages reciting the evidence it claims establishes that BIC, BIPI and Roxane ignored their separate corporate identities, the Court need not reach this issue because there is not sufficient

¹ In the labor law context, the “alter ego” doctrine has its own meaning and analysis. The test is more lenient and generally relates only to when successor liability should be imposed. As such, Courts distinguish the labor law alter ego concept from the more general corporate law concept of piercing the corporate veil between a parent and a subsidiary. *See Mass. Carpenters*, 139 F. 3d at 308 (“we think the policies generally served by various corporate veil-piercing approaches . . . address different interests than does the [labor law] alter ego doctrine”); *Nat’l Labor Relations Board v. Hospital San Rafael, Inc.*, 42 F.3d 45, 50 (1st Cir. 1994) (noting one “labor-law doctrine[]” “known colloquially as the alter ego doctrine, says that in certain situations one employer entity will be regarded as a continuation of a predecessor, and the two will be treated interchangeably for purposes of applying labor laws.”); *Trustees of the Graphic Comm. Int’l. Union v. Bjorkedal*, 516 F. 3d 719, 729 (8th Cir. 2008) (rejecting reliance “on cases applying the labor law standard of the alter ego doctrine, which ‘involves a more lenient standard for disregarding the corporate form than that employed in corporate law’ and which is ‘generally appropriate only when an employer reconstructs its business into another business in and effort to avoid its union obligations.’”) (internal citations omitted).

evidence that BIC or BIPI acted with fraudulent intent or improper purpose. *Mountzoures*, 376 F. Supp. 2d at 18; *163 Pleasant St.*, 960 F. 2d at 1093.²

The Government must prove fraudulent intent independently for BIC and BIPI to hold them both liable. The Government makes *no* attempt to demonstrate that BIPI used or treated Roxane as a sham corporation or acted in a blameworthy manner. BIPI is thus entitled to summary judgment. With respect to BIC, the Government's far-fetched theory that BIC, prompted by a 2000 subpoena related to AWP issues, fraudulently diverted Roxane's assets and purposefully left Roxane undercapitalized by virtue of a large dividend payment in 2002 is nothing more than unsupported supposition. (US Opp. to BIC/BIPI Mot. for SJ at 19-20) Other than the fact that the dividend payment was made after Roxane received a subpoena, which proves nothing, the Government cites not a single piece of evidence that the \$320 million dividend was motivated by any intent to prevent recovery in this case or otherwise leave Roxane without sufficient capital. The Government fails even to demonstrate that the decision-makers who authorized the dividend payment were aware of the subpoena.

In fact, the undisputed testimony of Roxane's corporate representative and tax officer is that the \$320 million payment, while greater than prior dividend payments, was made for legitimate business reasons based on specific events: 1) in 2001, Roxane received unbudgeted income of \$175 million from the sale of its palliative care product line; 2) because there was a significant tax incentive for BIC to distribute a dividend to its Canadian parent and subsequently to the German parent company prior to the end of 2002, all BIC subsidiaries paid higher than normal dividends to BIC in 2002; and 3) Roxane did not pay dividends to BIC on a regular basis

² While the question of when to pierce the corporate veil can be fact intensive, Courts should and do grant summary judgment on the issue when appropriate. *See, e.g., Mountzoures*, 376 F. Supp. 2d at 18-19 (granting summary judgment because plaintiff did not prove fraudulent intent).

prior to 2002, so the payment in 2002 “was a catch-up” for multiple past years. (Reply SOF ¶ 36) The evidence establishes that the \$320 million dividend payment “had nothing to do with any litigation.” (*Id.*) In the face of this undisputed hard evidence, the Government’s conjecture, based solely on an unremarkable temporal relationship between the dividend payment and a subpoena thirty months earlier, is insufficient to raise a genuine issue of fact regarding whether BIC used Roxane for a fraudulent purpose.³

Moreover, the mere fact that Roxane’s retained earnings and total equity were lower after the 2002 dividend payment and its ratio of liabilities to equity increased, does not mean Roxane was left undercapitalized. It is undisputed that even after 2002, Roxane had \$50-60 million in retained earnings and positive working capital, continued to earn substantial income and was able to fund its day-to-day operations and pay its debts as they came due.⁴ (SOF and Reply SOF ¶¶ 36-39) Certainly, as Roxane continues as a going concern today, funding its operations and generating income independently (Reply SOF ¶ 39), it cannot be concluded that the 2002 dividend payment “set [it] up for financial failure” or put it in a position where it “could not reasonably have been expected to meet its obligations.” *George Hyman Constr. Co. v. Gateman*, 16 F. Supp. 2d 129, 152-53 (D. Mass. 1998); *163 Pleasant St.*, 960 F. 2d at 1093. In fact, the undisputed testimony of Professor Macey confirms that Roxane was sufficiently capitalized

³ By 1999, Roxane was aware of government investigations into AWP’s and knew that some States, like Texas, were likely to bring lawsuits against Roxane. (Reply SOF ¶ 36) Even the Government’s subpoena was served in April 2000. If BIC wanted to shelter Roxane’s assets from the Government through dividend payments, it does not make logical sense to wait until late 2002 to do so.

⁴ The reason Roxane’s retained earnings and total equity were historically higher was not because it needed that level of retained earnings to be adequately capitalized but rather, for tax reasons, BIC had not paid dividends to its parent company and therefore did not receive regular dividends from its subsidiaries, including Roxane, instead deciding to leave the earnings at the operating unit level. (Reply SOF ¶ 36) The Government’s assertion that the 2002 dividend violated Boehringer Ingelheim guidelines is also incorrect. (Reply SOF ¶ 38)

throughout the relevant timeframe.⁵ (SOF ¶ 95; *see also* Reply SOF ¶ 39) No reasonable fact-finder could infer from Roxane’s capital position after 2002 that BIC had “looted [its] subsidiary” or was using Roxane “corruptly to avoid obligations.” Roxane hardly is or was a “shoestring operation.” *163 Pleasant St.*, 960 F. 2d at 1093-94.

B. Roxane Operated As A Separate Corporate Entity From BIC And BIPI.

The Government also fails to establish a genuine dispute regarding Roxane’s independence from its sister and parent. The Government does not dispute that Roxane was created and operated as a stand-alone company for many years, or that it maintained separate offices and headquarters, had its own employees, its own line of Roxane-labeled products it sold to its customers, a separate FDA labeler code and its own marketing and sales department. (*See* US Resp. to BIC/BIPI SOF ¶¶ 1, 5, 10-11, 14-15, 17, 54, 65, 75) In addition, the Government concedes that Roxane had a separate Board of Directors that maintained corporate formalities, kept separate financial statements and accounting records, did not inappropriately commingle funds with affiliates, earned income on a regular basis and has been able to pay its obligations. (*Id.* ¶¶ 21-22, 31, 36) Further, there is no dispute that BIPI and Roxane entered into arms-length contracts and agreements when Roxane manufactured for or licensed products from BIPI. (*Id.* ¶¶ 41-48) These hallmarks of a legitimate corporation are key factors courts consider in assessing independence in the alter ego context and alone warrant a finding that Roxane was a separate company. *See In re Acushnet River & New Bedford Harbor*, 675 F. Supp. 22, 35 (D. Mass. 1987); *InterGen N.V.*, 344 F. 3d at 149; *George Hyman Constr. Co.*, 16 F. Supp. 2d at 153-54.

⁵ The untimely and ad hoc data compilation prepared by the DOJ’s auditor (who has no qualifications or expertise in this area) comparing Roxane’s debt to equity ratio to its competitors is based on incomplete and unreliable data for a small number of companies that the Government has not even demonstrated are comparable to Roxane for these purposes, and for which the data suggests otherwise. (Reply SOF ¶ 39) This flawed “analysis” does not create a genuine issue of fact regarding the adequacy of Roxane’s capital, especially in light of Professor Macey’s reliable testimony.

Confronted with these undisputed facts, the Government points to various immaterial interactions and relationships between Roxane and BIPI. The facts prove nothing with regard to BIC and are insufficient with regard to BIPI. The un rebutted testimony of Professor Macey, an expert in the ordinary and standard practices of U.S. corporate groups, confirms that the interactions and contacts between Roxane and BIPI that the Government highlights are normal and typical among affiliated entities. (SOF ¶¶ 83-93) For example:

- Overlapping BIPI managers and supervisors, such as Mr. Berkle, Mr. King and Mr. Ciarelli, had high-level, non day-to-day responsibility for Roxane’s brand and branded generic products. (SOF ¶ 51, 79; Reply SOF ¶¶ 7, 51)
- A functional business unit concept, which maintained and respected the separate legal entities and corporate structures of Roxane and BIPI, was employed to take advantage of efficiencies and synergies that could be gained by coordinating overlapping aspects of the two businesses. (SOF ¶ 51; Reply SOF ¶¶ 7, 51)
- In the unique situation of ipratropium bromide, where Roxane launched the first generic of a BIPI brand name product, there was cooperation regarding the timing of the launch and limited discussions during which BIPI shared its experiences with the target markets. (SOF ¶¶ 67-69; Reply SOF ¶¶ 7, 53, 68)
- Roxane’s trade relations department occasionally assisted on BIPI products because, as a brand company, BIPI rarely needed such services. (Reply SOF ¶ 65)

The overlapping managers, isolated incidents of cooperation and high-level strategic coordination the Government relies upon merely reflect the natural cooperation and interaction expected among affiliated entities and, in light of the overall record of corporate separateness, provide no basis upon which to pierce the corporate veil in this case. *See In re Acushnet River*, 675 F. Supp. at 35 (declining to pierce veil where relationship “not ... at a level uncommon” for parents and subsidiaries); *In re Lupron Mktg. & Sales Practices Litig.*, 245 F. Supp. 2d 280, 292 (D. Mass. 2003) (finding that “customary incidents” of parent-subsidiary relationship provide no basis to pierce veil); *Amer. Med. Sys., Inc. v. Biolitec, Inc.*, 604 F. Supp. 2d 325, 330 (D. Mass. 2009) (holding that coordination and cooperation between corporate affiliates is insufficient to

justify veil piercing without evidence of control); *U.S. v. Bestfoods*, 524 U.S. 51, 64, n.10 (1998) (parent can be derivatively liable only where “so pervasively controlled [subsidiary] for a sufficiently improper purpose”).

II. BIC AND BIPI ARE NOT DIRECTLY LIABLE UNDER THE FCA.

Recognizing the weaknesses of its veil-piercing claim, the Government presses a direct liability theory against BIC and BIPI that it did not plead or otherwise assert until shortly before BIC and BIPI moved for summary judgment. The Government’s assertion that its imprecise use of the words “Defendants” and “they” throughout its complaint should have put BIC and BIPI on notice that it was asserting direct claims against them under the FCA is without merit. (US Opp. to BIC/BIPI Mot. for SJ at 9-10)

The Complaint is directed at conduct related solely to Roxane’s drugs and marketing practices. Further, it sets forth the basis for including BIC and BIPI at the beginning by alleging: “The management, supervision, control, reporting, and financial exchanges by and between BIC and its subsidiaries, BIPI and Roxane, are so *inextricably intertwined* that these defendants in effect operated as one single entity. BIC, BIPI, and Roxane acted in concert together to foster, facilitate, and promote the unlawful conduct alleged more specifically below.” (US First Am. Compl. at ¶ 19 (emphasis added)) In the next paragraph it describes more specific facts in support of its allegation that the companies acted as a single entity. (*Id.* at ¶ 20) As in the *Mountzoures* case, “the only theory” of parent liability “that can be inferred from the complaint” is an alter ego theory. *Mountzoures*, 376 F. Supp. 2d at 19-20 (complaint alleged that the defendants had “treated the [] [c]ompanies as a single entity”). This Court should follow the “well-settled” rule “that plaintiffs are generally not permitted to raise brand new theories of their case in opposition to a motion for summary judgment.” (*Id.*)

In any case, the Government cannot meet the strict falsity, scienter or causation requirements necessary to hold BIC and BIPI directly liable, and summary judgment in their favor is warranted on those grounds as well.

A. BIC's And BIPI's Liability Must Be Proven Individually On A Drug-By-Drug Basis.

This Court has repeatedly made clear that FCA liability stems from conduct related to specific drugs and AWP. It has required plaintiffs to allege the particular AWP for specific drugs they claim were false and to prove the falsity of those AWP on a drug-by-drug basis. *In re AWP Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003); *Mass. v. Mylan Labs.*, 608 F. Supp. 2d 127, 144, 154-55 (D. Mass. 2008). Accordingly, the Government identified nine Roxane drugs here. It would be inconsistent with this Court's prior rulings and defy logic if BIC or BIPI could be directly (as opposed to derivatively) liable under the FCA based on the purported falsity of AWP they did not set. To hold both BIC and BIPI liable for damages tied to nine Roxane drugs over a 10 year period, the Government must, at a minimum, demonstrate that each company actively participated in setting and reporting the AWP at issue and in marketing spreads for those drugs during the relevant timeframe. *See U.S. v. President & Fellows of Harvard College*, 323 F. Supp. 2d 151, 186 (D. Mass. 2004). In the absence of such proof, the Government cannot show that either BIC or BIPI *caused* submission of a false claim.

In addition, to establish a question of fact regarding the necessary scienter, the Government must come forward with some proof that BIC and BIPI actually knew about, deliberately ignored, or recklessly disregarded some statutory, regulatory, or contractual authority requiring that Roxane's AWP reflect actual acquisition costs. (*See* Roxane SJ Reply Br. at 7-10; Defs.' Comm. Br. 30-32 (filed August 28, 2009)) Thus, in addition to proving active participation in setting and reporting Roxane's AWP and marketing spreads, the Government

must also show that BIC or BIPI knew that Roxane's AWP's were false and knew that Medicare and Medicaid would use these "false" AWP's for reimbursement. *President & Fellows of Harvard College*, 323 F. Supp. 2d at 186-87.

B. The Circumstances Cited By The Government Do Not Raise Sufficient Factual Issues Supporting BIC's or BIPI's Direct Liability Under The FCA.

Unable to marshal the specific drug-by-drug and entity-by-entity facts necessary to establish direct liability under the FCA, the Government resorts to a "kitchen sink" approach, presenting any and all evidence it could find showing interactions or relationships between Roxane, BIC and BIPI. For purposes of the Government's direct liability contentions, however, nearly all of these facts are immaterial. For example, much of the Government's evidence relates generally to corporate structure issues, such as the implementation of a business unit concept, consolidation of certain departments and the overlapping supervisory roles of several BIPI employees. Without further evidence tying these structures or employees to the setting of AWP's or marketing of spreads on Subject Drugs, these facts prove nothing with regard to BIC's or BIPI's direct liability under the FCA.

Indeed, when one sorts through the hodgepodge of evidence the Government has thrown at the wall, it becomes abundantly clear that for most of the Subject Drugs for most of the time, the Government does not even attempt to create a disputed issue regarding BIC's or BIPI's participation in setting or reporting a relevant AWP. Rather, it takes a few facts related to a few drugs at single points in time and inappropriately attempts to bootstrap direct liability for both BIC and BIPI for all drugs over the entire relevant timeframe.

1. BIC is not directly liable for causing submission of false claims.

For seven of the Subject Drugs (azathioprine, diclofenac sodium, hydromorphone, ipratropium bromide, sodium polystyrene, Oramorph and Roxanol), the Government points to no

evidence that any BIC employee had any involvement whatsoever is setting or reporting AWP, or marketing the drugs, much less marketing the spread on the drugs with the requisite scienter. And its attempt to link BIC to the 2000 furosemide AWP increase or Roxicodone launch AWP based on the *potential* involvement of Mr. Gerstenberg fails as a matter of fact and law.

As an initial matter, the Government has not raised a material question of fact as to whether Mr. Gerstenberg actually approved the furosemide increase. Mr. Russillo testified that he could not recall whether he consulted with Mr. Gerstenberg prior to approving the AWP increase, and concluded, after reviewing all of the documents the Government relies upon, that he “probably did not.”⁶ (SOF ¶ 71; Reply SOF ¶¶ 53, 61-62) More importantly, as the Government concedes, Mr. Gerstenberg was both the President and CEO of BIC *and* the President and COO of Roxane at the time of the furosemide AWP change. (SOF ¶ 30) It is Mr. Russillo’s undisputed testimony that if he conferred with Mr. Gerstenberg regarding the AWP change, Mr. Gerstenberg “would have been acting as the President of Roxane.” (SOF ¶ 71; Reply SOF ¶¶ 53, 61-62) In fact, when asked more generally who he was required “to report to regarding marketing decisions for Roxane’s multisource products,” Mr. Russillo stated that “Mr. Gerstenberg was the president of Roxane Laboratories. As such, I had an obligation to keep him informed as to what was going on.”⁷ (*Id.*) In light of Mr. Russillo’s testimony, there is no basis

⁶ Mr. Russillo made clear that he did not need Mr. Gerstenberg’s authorization to approve price changes for Roxane’s multisource products, but would have consulted with Mr. Gerstenberg only “at his discretion.” (Reply SOF ¶¶ 53, 61-62)

⁷ The Government ignores this testimony and instead relies upon Mr. Russillo’s later testimony in response to more general questions that he reported to Mr. Gerstenberg “in his role as president and CEO of BIC” and was directed by Mr. Gerstenberg in that role to take over management of Roxane’s multisource business. (Reply SOF ¶¶ 30, 71) Of course, at the time Mr. Russillo was given responsibility for Roxane’s multisource business he was the President and COO of a separate BIC subsidiary, Ben Venue Laboratories, and thus, in that position, would have reported to (and continued to report to) Mr. Gerstenberg as the CEO of the parent company, BIC. (*Id.*) Further, even in his Roxane role, there may have been higher level strategy or organizational issues that Mr. Russillo discussed with Mr. Gerstenberg in his role at the parent company. However, as already described, when asked specifically who he reported to regarding Roxane marketing decisions and in what capacity he consulted Mr. Gerstenberg regarding Roxane multisource price increases to the extent he did, Mr. Russillo’s

to disregard the *Bestfoods* presumption that Mr. Gerstenberg was wearing his “Roxane hat” and acting on behalf of Roxane, not BIC, when making any decision related to Roxane’s drugs. *Bestfoods*, 524 U.S. at 68–70 (there is a presumption that when an employee with dual “hats” acts for the subsidiary, he is wearing his subsidiary hat and his actions cannot be imputed to the parent company). For the same reasons, to the extent Mr. Gerstenberg approved the launch AWP for Roxicodone in August 2000, he did so in his capacity as the President of Roxane.⁸

2. BIPI was not involved in AWP decisions for Roxane’s multisource drugs at issue.

The Government brings forth no evidence that BIPI participated or was complicit in setting or reporting AWP or marketing spreads for five of the six multisource drugs at issue: azathioprine, diclofenac sodium, furosemide, hydromorphone, and sodium polystyrene. And its evidence related to ipratropium bromide only emphasizes the thin reed upon which its direct liability theory rests. Specifically, the Government relies upon a single document and one meeting showing discussions with BIPI at the time Roxane launched ipratropium bromide in 1996. Such discussions were only natural since Roxane was launching the generic version of BIPI’s brand name ipratropium product. (Reply SOF ¶ 7) In the eight years Roxane sold the drug post-launch, the Government has not even a scintilla of proof that BIPI had anything to do with marketing Roxane’s product, much less setting or reporting prices or marketing the spread

undisputed testimony is that Mr. Gerstenberg was acting as President of Roxane in those instances. (SOF ¶ 71; Reply SOF ¶¶ 30, 61-62, 71)

⁸ As discussed in greater detail below, the Government’s contention that Mr. Gerstenberg was acting in his capacity as the CEO of BIC in approving Roxicodone’s AWP based on a May 2001 *draft* pricing policy requiring approval from the CEO of BIC is spurious. The policy was not even drafted until nine months *after* the launch of Roxicodone. (Reply SOF ¶ 51)

on the product.⁹ Moreover, even the 1996 evidence does not raise a material issue of fact regarding BIPI's involvement in setting the launch AWP for Roxane's ipratropium bromide.

First, contrary to the Government's assertion, there was no meeting where it was "agreed" between BIPI and Roxane that the AWP would be set at 10% less than Atrovent's. (US Opp. To BIC/BIPI Mot. for S.J. at 6, 12) The meeting memo reflects no discussion about how the AWP should be set; rather, it simply states that "[i]t should be noted that the AWP for IBUDV will be 10% below Atrovent's AWP at the time of launch." The only fair inference from this statement is that the AWP had already been determined by Roxane. (Reply SOF ¶¶ 7, 68) Indeed, the AWP for ipratropium bromide was set at 10% below the brand in accordance with "the traditional parameters of a generic product" and standard practice at Roxane. (*Id.*)

Second, Mr. Tupa's testimony that he "believed" Mr. Berkle approved the ipratropium bromide marketing plan at the time of launch hardly establishes a material issue of fact regarding BIPI's approval of the AWP, especially in light of Mr. Berkle's testimony. (US Opp. To BIC/BIPI Mot. for SJ at 6, 12) Mr. Berkle could not recall approving the marketing plan, stating that "I would not have had access necessarily to the detailed marketing plan. I was concerned with the overall forecasts and general strategies, but not in the nitty-gritty of the marketing plan. Mr. Wojta [the President of Roxane at the time] really had the responsibility and the authority to approve that . . ." (Reply SOF ¶¶ 7, 68) Further, Mr. Berkle unequivocally testified that "anything to do with the establishment of pricing [for ipratropium bromide] was decided within

⁹ The Government alleges that BIPI and Roxane engaged in "joint marketing" efforts (US Opp. to BIC/BIPI Mot. for SJ at 1-2, 4-5), but the evidence it cites reflects, at most, three instances where BIPI and Roxane coordinated contract bids for their individual products for overlapping customers for the benefit of both companies and their customers. (Reply SOF ¶ 9) The evidence does not show that BIPI was involved in setting the Roxane contract prices contained in the bids, much less that BIPI had anything to do with setting AWP's or overall marketing strategies for Roxane products.

the Roxane organization, had to be approved by . . . the president of the Roxane organization.”
(*Id.* (“I was not involved in the marketing or pricing of Ipratropium Bromide”))

3. The Government’s evidence is insufficient to establish direct liability for BIPI with regard to Roxane’s brand and branded generic drugs.

The bulk of the evidence the Government raises in support of its direct liability claim is limited to Roxane’s brand and branded generic products (Oramorph SR, Roxanol and Roxicodone). Those products had a natural overlap with BIPI’s brand drug business that led to greater efforts to achieve synergies and efficiencies and to leverage the experience and expertise of BIPI employees for the benefit of Roxane. Yet the evidence falls short of demonstrating that BIPI set or reported AWP’s for these drugs or was involved in alleged marketing of the spread with the required intent.

First, the Government repeatedly misleads this Court when it claims that a “common pricing policy and procedure” existed that was applicable to both BIPI’s and Roxane’s branded/branded generic products and required approval from a BIPI pricing committee, Mr. Berkle and Mr. Gerstenberg, as the CEO of BIC. (US Opp. to BIC/BIPI Mot. for SJ at 5-6, 11, 14) The Government’s only support for this statement is a *May 2001 draft* common pricing policy that was circulated for comments. (Reply SOF ¶ 51) No evidence shows that this proposed policy was ever finalized or that any AWP for a Roxane brand/branded generic product was approved under this policy. It is impossible for the Roxicodone 15/30 mg AWP’s to have been approved according to this policy, as the Government claims, as the products were launched nine months *before* the draft policy was even written. (*Id.*) And the Government points to no other AWP decision for any other Subject Drug that it claims was set or approved according to this alleged pricing policy. Indeed, the only Roxane products the policy would have applied to

had it been finalized were divested only four months after the draft was circulated. (SOF ¶ 81; Reply SOF ¶ 51)

Second, that certain BIPI employees, such as Mr. Ciarelli, Mr. King and Mr. Leonetti, held supervisory roles in the sales and marketing chain of command for Roxane's brand and branded generic products for a limited period of time (October 1998 – September 2001) cannot form the basis of FCA liability for BIPI. The undisputed testimony is that the BIPI supervisors were given high-level oversight roles with regard to Roxane's brand/branded generic products, but did not get involved in the day-to-day activities. They continued to be handled by the Roxane department directors.¹⁰ (SOF ¶ 79; Reply SOF ¶ 51) This is confirmed by the fact that the Government points to only a single instance where it appears that BIPI personnel were involved in an AWP decision for a Subject Drug, the launch of Roxicodone in 2000. Thus Roxicodone is not, as the Government claims, demonstrative of more on-going or widespread involvement of BIPI in the marketing decisions for Roxane's brand/branded generic products. Further, even for Roxicodone, Roxane employees and consultants drafted the proposal setting the AWP. (Reply SOF ¶ 51) BIPI employees merely approved the plan proposed by Roxane. (*Id.*)

Moreover, to the extent the BIPI-based supervisors had any material involvement in AWP or marketing decisions for Roxicodone or other Roxane brand/branded generic drugs, they were acting on behalf of Roxane, and under the *Bestfoods* presumption their conduct cannot be imputed to BIPI. *Bestfoods*, 524 U.S. at 68-70. The Government's claim that the BIPI personnel had to be formal employees of and paid by Roxane to have a "Roxane hat" to wear has no basis

¹⁰ Thus, while the Government makes much of Mr. Ciarelli's statement that he had "ongoing responsibility" for reporting AWP's for Roxane's brand/branded generic drugs to the compendia, his testimony makes clear that he is referring only to the fact that Mr. Powers, Roxane's Director of Contracts, was responsible for reporting to the compendia and Mr. Powers reported to him for a period of time. (Reply SOF ¶¶ 14, 51) There is no indication that Mr. Ciarelli was involved in reporting Roxane AWP's to the pricing compendia except for a period of time as Mr. Powers' boss.

in law or fact. First, the two cases cited by the Government did not analyze this issue or hold that a formal employee or compensation relationship was required. *Bestfoods*, 524 U.S. at 69-71; *U.S. v. Kayser-Roth Corp.*, 272 F. 3d 89, 103 (1st Cir. 2001). Nor, as Professor Macey testified, is it common practice among U.S. corporations for personnel with two “hats” to be employed or paid separately by each. (SOF and Reply SOF ¶ 93 (for employees with dual roles, the “overwhelming business practice in the United States is to have people receive a single paycheck”))

Second, to base the determination of whether corporate actors have a “hat to wear” on their technical employment status, as the Government suggests, rather than their designated roles and responsibilities, would put form over substance. Unlike the *Bestfoods* situation, where the parent employee had not been assigned any role within the management or organizational structure of the subsidiary (*Bestfoods*, 524 U.S. at 72; *Best Foods v. Aerojet-General Corp.*, 173 F. Supp. 2d 729, 741-45, 749-51 (W.D. Mich. 2001), the BIPI personnel in this case were given positions and ongoing supervisory responsibility for Roxane’s brand/branded generic products as part of a reorganization announced through an official company bulletin. (SOF ¶ 78; Reply SOF ¶ 51) Mr. King, for example, became the “Head of BU BIPI/RLI Branded Sales.” (*Id.*) The employees were inserted as an additional level of oversight within Roxane’s sales and marketing structure and listed on Roxane’s organizational chart. (Reply SOF ¶¶ 14, 51)

In addition, because Roxane and BIPI had distinct products, work related to Roxane’s products was naturally only done because of and within the scope of the roles the employees had been given at Roxane, and inured solely to Roxane’s benefit. (SOF ¶¶ 92-94) This is not a situation where the actions were “plainly contrary to the interests of the subsidiary yet nonetheless advantageous to the parent.” *Bestfoods*, 524 U.S. at 70 n. 13 (stating the

presumption “waned” in those circumstances). In fact, quite the opposite, as BIPI received no benefit from the work these employees did related to Roxane’s products. Under these circumstances, the *Bestfoods* presumption that these supervisors had and were wearing a “Roxane hat” such that Roxane is responsible for their conduct with regard to Roxicodone and any other Roxane product should logically and equitably apply.

CONCLUSION

For the foregoing reasons, summary judgment should be granted in favor of BIC and BIPI on all claims.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on September 22, 2009, a copy to LexisNexis File and Serve for posting and notification to all parties.

By: /s/ Eric T. Gortner
Eric. T. Gortner